

§ 5.71 Termination of exemptions for new drugs for investigational use in human beings and in animals.

(a) The following officials, for drugs under their jurisdiction, are authorized to perform all the functions of the Commissioner of Food and Drugs on the termination of exemptions for new drugs (including those that are biological products which are subject to the licensing provisions of the Public Health Service Act) for investigational use in human beings under § 312.44 of this chapter and in animals under § 312.160 of this chapter:

(1) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(2) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(b) The following officials, for drugs under their jurisdiction, are authorized to terminate exemptions for new drugs for investigational use when sponsors fail to submit an annual progress report under § 312.44(b)(1)(viii) of this chapter:

(1) The Directors and Deputy Directors of the Offices of Drug Evaluation I and Drug Evaluation II, CDER.

(2) The Directors and Deputy Directors in the divisions in the Offices of Drug Evaluation I and Drug Evaluation II and the Director and supervisory medical officers, Pilot Drug Evaluation Staff, Office of the Center Director, CDER.

(3) The Director and Deputy Director, Office of Biological Product Review, CBER.

(4) The Director and Deputy Director, Division of Biological Investigational New Drugs, Office of Biological Product Review.

(c) The following officials, for drugs under their jurisdiction, are authorized to make the findings set forth in § 312.44(b) of this chapter and to notify sponsors and invite correction before termination action on such exemptions:

(1) The Directors and Deputy Directors of the Offices of Drug Evaluation I and Drug Evaluation II, CDER.

(2) The Directors and Deputy Directors in the divisions in the Offices of Drug Evaluation I and Drug Evaluation II and the Director and supervisory

medical officers, Pilot Drug Evaluation Staff, Office of the Center Director, CDER.

(3) The Director and Deputy Director, Office of Biological Product Review, CBER.

(4) The Director and Deputy Director, Division of Biological Investigational New Drugs, Office of Biological Product Review.

(d) The following officials are authorized to perform all functions of the Commissioner of Food and Drugs with regard to the termination of new animal drugs for investigational use in animals under § 511.1 of this chapter:

(1) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

[49 FR 14934, Apr. 16, 1984, as amended at 50 FR 14094, Apr. 10, 1985; 52 FR 7829, Mar. 13, 1987; 54 FR 8318, Feb. 28, 1989; 55 FR 51688, Dec. 17, 1990]

§ 5.72 Authority to approve and to withdraw approval of a charge for investigational new drugs.

The following officials, for drugs under their jurisdiction, are authorized to perform all the functions of the Commissioner of Food and Drugs to approve a charge and to withdraw approval to charge for investigational drugs in a clinical trial under an investigational new drug application under § 312.7(d)(1) of this chapter:

(a) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

[55 FR 5445, Feb. 15, 1990]

§ 5.73 Certification of insulin.

The following officials are authorized to certify or reject batches of drugs containing insulin pursuant to section 506(a) of the Federal Food, Drug, and Cosmetic Act:

(a) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Office of Compliance, CDER.